C. Remarks

The claims are 24-38, with claim 24 being the sole independent claim. Claims 24 and 25 have been amended to clarify the invention. More particularly, the claims have been amended to make it clear that rendering the active agent less soluble is a required step, which may be performed prior to or at the same time as system formation. Applicants submit that the amendments are fully supported by the application as originally filed and that no new matter has been added. Reconsideration of the present claims is respectfully requested.

Claims 24-38 stand rejected for obviousness-type double patenting in view of claims 1, 2 and 4-16 of U.S. Patent No. 6,726,928. As noted in the previous response, Applicants respectfully traverse this rejection, but in an effort to expedite prosecution of this case, it is Applicants' present intention to file a terminal disclaimer to overcome this rejection when all the other issues have been resolved.

Claims 24, 26-30, 32-34 and 36 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Gregory* (U.S. Patent No. 4,305,502) in view of *Ince* (U.S. Patent No. 4,657,929). Claims 24-34 and 37 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Gregory* in view of *Mughal* (U.S. Patent No. 4,465,838). Claims 24-35, 37 and 38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Gregory* in view of *Koparkar* (U.S. Patent No. 5,284,662). Applicants respectfully traverse these rejections.

At the outset, Applicants would like to incorporate by reference herein the entirety of the previously set forth arguments regarding the deficiencies of *Gregory* as a primary reference. Those arguments make the point that there is simply no teaching in *Gregory* about rendering the active substance less soluble. As such a step is explicitly required in the presently amended claims, it is respectfully submitted that claim 24 and its dependent claims are clearly distinguishable over *Gregory* whether viewed alone or in any combination with *Ince, Mughal* or *Koparkar*.

The Examiner takes the position that "[t]he method of formulation of a pharmaceutically active agent into a readily dissolving, orally administered tablet taught by Gregory et al. has the inherent property of rendering the active substance less soluble and more palatable." Applicants respectfully submit that this is simply not the case; the method of formulation, i.e., formation of a solution or suspension in the presence of a carrier material, does not lead to a less soluble form of the pharmaceutically active substance. Active steps must be made to achieve the less soluble form. In fact, the present specification at page 6, line 12, through page 10, line 5, details the various means through which the pharmaceutically active substance can be rendered less soluble, i.e., insolubilized. None of these techniques nor the general concept of reducing the solubility of an active are disclosed or suggested by *Gregory*.

None of the secondary references *Ince, Mughal* and *Koparkar* remedy this basic deficiency of *Gregory*. *Ince* is cited by the Examiner merely for its disclosure related to domperidone, while *Koparkar* is similarly cited by the Examiner for its disclosure related to lorazepam and loperamide. Neither of these references teaches or suggests rendering an active agent less soluble.

In addition, while *Mughal* does teach the formation of a more palatable form of oxaprozin by selection of a less soluble salt, it still fails to remedy the deficiencies of *Gregory* since it would be counterintuitive for one of ordinary skill in the art to combine the teachings of *Gregory* and *Mughal*. More particularly, given *Gregory*'s logical preference for readily soluble active ingredients in the formation of rapidly disintegrating dosage forms, one of ordinary skill in the art would not look to decrease the solubility of the intended active as such a step would seem to be opposed to the desired end point. *Gregory*'s use of lorazepam (which is not particularly bad tasting) does not teach otherwise; while lorazepam may be described as a drug which is "slightly soluble" or "poorly water soluble", there is simply no disclosure of a method step which makes

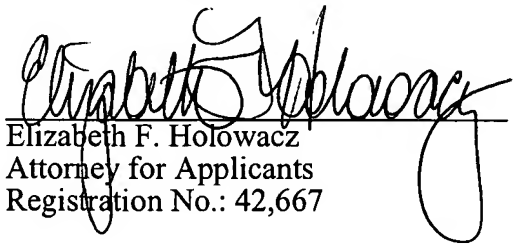
lorazepam even less soluble than its original form. Exactly such a step is what is required by the present claims.

In sum, no combination of *Gregory, Ince, Mughal* and *Koparkar* renders the present invention obvious. Simply put, the cited prior art fails to disclose or suggest certain key features of the present invention, namely the insolubilization of an active substance with an unacceptable taste for formulation in a fast dissolving dosage form. For at least these reasons, Applicants submit that no combination of *Gregory*, *Ince, Mughal* and *Koparkar* renders obvious claim 24 or its dependent claims and respectfully request withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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